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Attorneys for Plaintiffs
Shire LLC and Shire Development Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SHIRE LLC, and SHIRE DEVELOPMENT INC. Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., MYLAN INC., JOHNSON MATTHEY PHARMACEUTICAL MATERIALS and JOHNSON MATTHEY INC. Defendants.	))))))))))))	C.A. No. _____

COMPLAINT

Plaintiffs Shire LLC and Shire Development Inc. (collectively "Shire"), by its undersigned attorneys, for its Complaint against defendants Mylan Pharmaceuticals, Inc. and

Mylan Inc. (collectively, "Mylan") and defendants Johnson Matthey Pharmaceutical Materials and Johnson Matthey Inc. (collectively, "Johnson Matthey") (Mylan and Johnson Matthey herein after collectively, "Defendants") herein, allege as follows:

NATURE OF THE ACTION

1. This action is related to the following cases pending in the District of New Jersey: *Shire LLC et al. v. Actavis Elizabeth LLC et al.*, Civil Action No. 2:11-04053-SRC-MAS; *Shire LLC et al. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 2:11-03781-SRC-MAS; *Shire LLC et al. v. Roxane Laboratories, Inc.*, Civil Action No. 2:11-03886-SRC-MAS; and *Shire LLC et al. v. Sandoz Inc.*, Civil Action No. 3:11-03787-PGS-LHG, which have all been consolidated under *Shire LLC et al. v. Amneal Pharmaceuticals, LLC et al.*, Civ. Action No. 2:11-03781-SRC-MAS (consolidated).

2. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 7,105,486 ("the '486 patent") (attached as Exhibit A hereto); United States Patent No. 7,223,735 ("the '735 patent") (attached as Exhibit B hereto); United States Patent No. 7,655,630 ("the '630 patent") (attached as Exhibit C hereto); United States Patent No. 7,659,253 ("the '253 patent") (attached as Exhibit D hereto); United States Patent No. 7,659,254 ("the '254 patent") (attached as Exhibit E hereto); United States Patent No. 7,662,787 ("the '787 patent") (attached as Exhibit F hereto); United States Patent No. 7,671,030 ("the '030 patent") (attached as Exhibit G hereto); United States Patent No. 7,671,031 ("the '031 patent") (attached as Exhibit H hereto); United States Patent No. 7,674,774 ("the '774 patent") (attached as Exhibit I hereto); United States Patent No. 7,678,770 ("the '770 patent") (attached as Exhibit J hereto); United States Patent No. 7,678,771 ("the '771 patent") (attached as Exhibit K hereto); United States Patent No. 7,687,466 ("the '466 patent")

(attached as Exhibit L hereto); United States Patent No. 7,687,467 ("the '467 patent") (attached as Exhibit M hereto); United States Patent No. 7,718,619 ("the '619 patent") (attached as Exhibit N hereto); and United States Patent No. 7,723,305 ("the '305 patent") (attached as Exhibit O hereto).

THE PARTIES

3. Plaintiff Shire LLC is a corporation organized and existing under the laws of the State of Kentucky, having a place of business at 9200 Brookfield Court, Florence, Kentucky 41042.

4. Plaintiff Shire Development Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 725 Chesterbrook Boulevard, Wayne, Pennsylvania 19087.

5. Upon information and belief, Mylan Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

6. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

7. Upon information and belief, Mylan Pharmaceuticals, Inc. is a wholly owned subsidiary of Mylan Inc.

8. Upon information and belief, Mylan Pharmaceuticals, Inc. acts at the direction of, under the control of, and for the direct benefit of Mylan Inc. and is controlled and/or dominated by Mylan Inc.

9. Upon information and belief, Johnson Matthey Pharmaceutical Materials (also known as Johnson Matthey Inc. - Pharmaceutical Materials and/or Johnson Matthey

Pharmaceutical Materials - USA) is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 2003 Nolte Drive, West Deptford, New Jersey 08066.

10. Upon information and belief, Johnson Matthey Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a place of business at 435 Devon Park Drive, Suite 600, Wayne, Pennsylvania 19087.

11. Upon information and belief, Johnson Matthey Pharmaceutical Materials is a wholly owned subsidiary of Johnson Matthey Inc.

12. Upon information and belief, Johnson Matthey Pharmaceutical Materials acts at the direction of, under the control of, and for the direct benefit of Johnson Matthey Inc. and is controlled and/or dominated by Johnson Matthey Inc.

JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

14. This Court has personal jurisdiction over Mylan Pharmaceuticals, Inc. because, inter alia, of its continuous and systematic contacts with this judicial district. Upon information and belief, Mylan Pharmaceuticals, Inc. derives substantial revenue from articles used and consumed in this judicial district. Upon information and belief, Mylan Pharmaceuticals, Inc. markets products through distributors with retail branch locations in this judicial district.

15. This Court has personal jurisdiction over Mylan Inc. because, inter alia, of its continuous and systematic contacts with this judicial district. Upon information and belief, Mylan Inc. markets, sells, and/or distributes pharmaceutical products in this judicial district through one or more of its wholly-owned subsidiaries, including Mylan Pharmaceuticals, Inc.

Mylan Inc.'s 2008 Annual Report stated, "[Mylan Pharmaceuticals, Inc.] is our primary U.S. pharmaceutical research, development, manufacturing, marketing and distribution subsidiary."

16. This Court has personal jurisdiction over Johnson Matthey Pharmaceutical Materials. Johnson Matthey Pharmaceutical Materials has submitted to personal jurisdiction in this Court because, inter alia, it resides and is doing business in New Jersey.

17. This Court has personal jurisdiction over Johnson Matthey Inc. because, inter alia, it is doing business in New Jersey and has continuous and systematic contacts with this judicial district, including through its wholly-owned subsidiary Johnson Matthey Pharmaceutical Materials.

18. Upon information and belief, Johnson Matthey manufactures, uses, markets, sells, and/or distributes pharmaceutical materials and services, including active pharmaceutical ingredients, in this judicial district.

19. Upon information and belief, this Court has specific personal jurisdiction over Johnson Matthey because, inter alia, it purposely registered the Johnson Matthey Pharmaceutical Materials facility in West Deptford, New Jersey, with the federal Drug Enforcement Agency ("DEA") as a manufacturer of lisdexamfetamine dimesylate active pharmaceutical ingredient ("API") for sale to Johnson Matthey's customer(s), which upon information and belief, as Johnson Matthey's Drug Master File ("DMF") for lisdexamfetamine dimesylate is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, includes Mylan and as such is purposely manufacturing, using, offering for sale, selling, and supporting its customer(s)' Abbreviated New Drug Applications ("ANDA") for generic lisdexamfetamine dimesylate capsules, including Mylan's ANDA No. 202835 ("the Mylan ANDA").

20. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FACTS AS TO ALL COUNTS

21. Shire Development Inc. is the owner of New Drug Application ("NDA") No. 021977, which was approved by the FDA for the manufacture and sale of Vyvanse®. Vyvanse® is the trade name for lisdexamfetamine dimesylate, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg capsules for oral administration and is approved for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD").

22. Pursuant to 21 U.S.C. § 355(b)(1), the '486 patent, the '735 patent, the '630 patent, the '253 patent, the '254 patent, the '787 patent, the '030 patent, the '031 patent, the '774 patent, the '770 patent, the '771 patent, the '466 patent, the '467 patent, the '619 patent, and the '305 patent are listed in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering the Vyvanse® product.

23. Shire LLC has been assigned, and currently owns, the rights to the '486 patent, the '735 patent, the '630 patent, the '253 patent, the '254 patent, the '787 patent, the '030 patent, the '031 patent, the '774 patent, the '770 patent, the '771 patent, the '466 patent, the '467 patent, the '619 patent, and the '305 patent (collectively, "the Patents-in-Suit").

24. The '486 patent, titled "Abuse-Resistant Amphetamine Compounds," was duly and legally issued on September 12, 2006. The '486 patent is generally directed to methods of treatment using L-lysine-d-amphetamine.

25. The '735 patent, titled "Abuse Resistant Lysine Amphetamine Compounds," was duly and legally issued on May 29, 2007. The '735 patent is generally directed to pharmaceutical compositions comprising L-lysine-d-amphetamine.

26. The ’630 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was duly and legally issued on February 2, 2010. The ’630 patent is generally directed to the compound, L-lysine-d-amphetamine dimesylate.

27. The ’253 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was duly and legally issued on February 9, 2010. The ’253 patent is generally directed to crystalline lisdexamphetamine dimesylate.

28. The ’254 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was duly and legally issued on February 9, 2010. The ’254 patent is generally directed to methods of treatment comprising L-lysine-d-amphetamine.

29. The ’787 patent, titled “Abuse Resistant Lysine Amphetamine Compounds” was duly and legally issued on February 16, 2010. The ’787 patent is generally directed to L-lysine-d-amphetamine compounds.

30. The ’030 patent, titled “Abuse-Resistant Amphetamine Prodrugs” was duly and legally issued on March 2, 2010. The ’030 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

31. The ’031 patent, titled “Abuse-Resistant Amphetamine Prodrugs” was duly and legally issued on March 2, 2010. The ’031 patent is generally directed to methods of delivering amphetamines.

32. The ’774 patent, titled “Abuse-Resistant Amphetamine Prodrugs” was duly and legally issued on March 9, 2010. The ’774 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

33. The ’770 patent, titled “Abuse-Resistant Amphetamine Prodrugs” was duly and legally issued on March 16, 2010. The ’770 patent is generally directed to methods of treatment comprising L-lysine-d-amphetamine.

34. The ’771 patent, titled “Abuse-Resistant Amphetamine Prodrugs” was duly and legally issued on March 16, 2010. The ’771 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

35. The ’466 patent, titled “Abuse-Resistant Amphetamine Prodrugs” was duly and legally issued on March 30, 2010. The ’466 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

36. The ’467 patent, titled “Abuse-Resistant Amphetamine Prodrugs” was duly and legally issued on March 30, 2010. The ’467 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

37. The ’619 patent, titled “Abuse-Resistant Amphetamine Prodrugs” was duly and legally issued on May 18, 2010. The ’619 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

38. The ’305 patent, titled “Abuse-Resistant Amphetamine Prodrugs” was duly and legally issued on May 25, 2010. The ’305 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

39. Upon information and belief, Mylan Pharmaceuticals, Inc. and Mylan Inc. worked in concert to prepare, submit, and file the Mylan ANDA to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic lisdexamfetamine dimesylate capsules, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and

70 mg, for oral administration ("the Mylan Proposed Product").

40. Upon information and belief, according to the FDA's website, Johnson Matthey submitted a Type II DMF for lisdexamfetamine dimesylate API, No. 22442 ("Johnson Matthey's DMF"), to the FDA on or about January 27, 2009.

41. Upon information and belief, Johnson Matthey makes, uses, sells, offers for sale and/or imports lisdexamfetamine dimesylate API and, upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, Johnson Matthey makes, uses, sells, offers for sale and/or imports the lisdexamfetamine dimesylate API in the Mylan Proposed Product.

42. Upon information and belief, pursuant to 21 C.F.R. § 314.420, Johnson Matthey is authorizing the FDA to reference and review its lisdexamfetamine dimesylate API DMF No. 22442 in support of the Mylan ANDA and provided Mylan with written authorization to submit to the FDA in the Mylan ANDA.

43. Upon information and belief, Johnson Matthey registered the Johnson Matthey Pharmaceutical Materials facility in West Deptford, New Jersey, with the DEA as a manufacturer of lisdexamfetamine dimesylate API.

44. Upon information and belief, Johnson Matthey manufactures its lisdexamfetamine dimesylate API in West Deptford, New Jersey.

45. Upon information and belief, Johnson Matthey is a prime mover in the chain of events leading to infringement.

46. Mylan sent letters to Shire Pharmaceuticals, Inc. and Shire LLC purporting to provide notification that the Mylan ANDA was amended to contain certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") with regard to the '486 patent, the '735 patent, the '630 patent, the '253 patent, the '254 patent, the '787 patent, the '030 patent, the '031 patent, the '774 patent, the '770 patent, the '771 patent, the '466 patent, the '467 patent, the '619 patent, and the '305 patent ("the Mylan Notice Letters").

47. Mylan previously sent a letter to Shire Pharmaceuticals, Inc. and Shire LLC purporting to provide notification that the Mylan ANDA contains a paragraph IV certification with regard to United States Patent No. 7,700,561 ("the '561 patent"). Shire filed suit against Mylan within forty-five days of receipt of this letter for patent infringement of the '561 patent in the United States District Court for the Eastern District of New York on July 14, 2011, Civil Action No. 1:11-03414-RRM-VVP.

48. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

49. The Mylan Notice Letters do not assert non-infringement for each and every claim of each and every patent for which Mylan has made a paragraph IV certification.

50. The Mylan Notice Letters do not provide a full and detailed explanation of Mylan's factual and legal basis of invalidity and/or unenforceability for each and every claim of each and every patent for which Mylan has made a paragraph IV certification.

FIRST COUNT
(Infringement of the '486 Patent by Defendants)

51. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

52. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

53. Upon information and belief, Mylan included a paragraph IV certification to the '486 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '486 patent.

54. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

55. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

56. The inclusion of a paragraph IV certification to the ’486 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the ’486 patent is an act of infringement by Mylan of one or more claims of the ’486 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

57. Upon information and belief, Mylan’s commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the ’486 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

58. Upon information and belief, as Johnson Matthey’s DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA’s website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson Matthey.

59. Upon information and belief, the inclusion of Johnson Matthey’s written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the ‘486 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

60. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

61. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '486 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

62. Upon information and belief, Defendants are aware of the existence of the '486 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '486 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

63. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

SECOND COUNT
(Infringement of the '735 Patent by Defendants)

64. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

65. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

66. Upon information and belief, Mylan included a paragraph IV certification to the '735 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '735 patent.

67. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

68. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

69. The inclusion of a paragraph IV certification to the '735 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '735 patent is an act of infringement by Mylan of one or more claims of the '735 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

70. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '735 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

71. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson Matthey.

72. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the '735 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

73. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

74. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '735 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

75. Upon information and belief, Defendants are aware of the existence of the '735 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '735 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

76. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

THIRD COUNT
(Infringement of the '630 Patent by Defendants)

77. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

78. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

79. Upon information and belief, Mylan included a paragraph IV certification to the '630 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '630 patent.

80. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

81. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

82. The inclusion of a paragraph IV certification to the ’630 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the ’630 patent is an act of infringement by Mylan of one or more claims of the ’630 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

83. Upon information and belief, Mylan’s commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the ’630 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

84. Upon information and belief, as Johnson Matthey’s DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA’s website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson Matthey.

85. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the '630 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly in a cooperative venture, including by inducement and/or contributory infringement.

86. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

87. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '630 patent directly under 35 U.S.C. § 271(a) and/or indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

88. Upon information and belief, Defendants are aware of the existence of the '630 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '630 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

89. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

FOURTH COUNT
(Infringement of the '253 Patent by Defendants)

90. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

91. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

92. Upon information and belief, Mylan included a paragraph IV certification to the '253 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '253 patent.

93. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

94. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

95. The inclusion of a paragraph IV certification to the '253 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '253 patent is an act of infringement by Mylan of one or more claims of the '253 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

96. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '253 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

97. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson Matthey.

98. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the '253 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly in a cooperative venture, including by inducement and/or contributory infringement.

99. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

100. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '253 patent directly under 35 U.S.C. § 271(a) and/or indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

101. Upon information and belief, Defendants are aware of the existence of the '253 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '253 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

102. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

FIFTH COUNT
(Infringement of the '254 Patent by Defendants)

103. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

104. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

105. Upon information and belief, Mylan included a paragraph IV certification to the '254 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '254 patent.

106. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

107. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

108. The inclusion of a paragraph IV certification to the ’254 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the ’254 patent is an act of infringement by Mylan of one or more claims of the ’254 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

109. Upon information and belief, Mylan’s commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the ’254 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

110. Upon information and belief, as Johnson Matthey’s DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA’s website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson Matthey.

111. Upon information and belief, the inclusion of Johnson Matthey’s written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the ‘254 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

112. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

113. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '254 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

114. Upon information and belief, Defendants are aware of the existence of the '254 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '254 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

115. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

SIXTH COUNT

(Infringement of the '787 Patent by Defendants)

116. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

117. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale and/or distribution of the Mylan Proposed Product.

118. Upon information and belief, Mylan included a paragraph IV certification to the '787 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '787 patent.

119. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

120. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

121. The inclusion of a paragraph IV certification to the '787 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '787 patent is an act of infringement by Mylan of one or more claims of the '787 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

122. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '787 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

123. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson Matthey.

124. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the '787 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly in a cooperative venture, including by inducement and/or contributory infringement.

125. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

126. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '787 patent directly under 35 U.S.C. § 271(a) and/or indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

127. Upon information and belief, Defendants are aware of the existence of the '787 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '787 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

128. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

SEVENTH COUNT
(Infringement of the '030 Patent by Defendants)

129. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

130. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

131. Upon information and belief, Mylan included a paragraph IV certification to the '030 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '030

patent.

132. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

133. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

134. The inclusion of a paragraph IV certification to the '030 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '030 patent is an act of infringement by Mylan of one or more claims of the '030 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

135. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '030 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

136. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson Matthey.

137. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the '030 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

138. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

139. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '030 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

140. Upon information and belief, Defendants are aware of the existence of the '030 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '030 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

141. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

EIGHTH COUNT

(Infringement of the '031 Patent by Defendants)

142. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

143. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

144. Upon information and belief, Mylan included a paragraph IV certification to the '031 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '031 patent.

145. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

146. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

147. The inclusion of a paragraph IV certification to the '031 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '031 patent is an act of infringement by Mylan of one or more claims of the '031 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

148. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '031 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

149. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson

Matthey.

150. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the '031 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

151. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

152. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '031 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

153. Upon information and belief, Defendants are aware of the existence of the '031 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '031 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

154. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

NINTH COUNT
(Infringement of the '774 Patent by Defendants)

155. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

156. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

157. Upon information and belief, Mylan included a paragraph IV certification to the '774 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '774 patent.

158. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

159. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

160. The inclusion of a paragraph IV certification to the '774 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '774 patent is an act of infringement by Mylan of one or more claims of the '774 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

161. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '774 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

162. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson Matthey.

163. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the '774 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

164. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

165. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '774 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

166. Upon information and belief, Defendants are aware of the existence of the '774 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '774 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

167. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

TENTH COUNT
(Infringement of the '770 Patent by Defendants)

168. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

169. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

170. Upon information and belief, Mylan included a paragraph IV certification to the '770 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '770 patent.

171. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

172. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

173. The inclusion of a paragraph IV certification to the '770 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '770 patent is an act of infringement by Mylan of one or more claims of the '770 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by

inducement and/or contributory infringement.

174. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '770 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

175. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson Matthey.

176. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the '770 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

177. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

178. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '770 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

179. Upon information and belief, Defendants are aware of the existence of the '770 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '770 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

180. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

ELEVENTH COUNT
(Infringement of the '771 Patent by Defendants)

181. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

182. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

183. Upon information and belief, Mylan included a paragraph IV certification to the '771 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '771 patent.

184. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

185. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

186. The inclusion of a paragraph IV certification to the '771 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '771 patent is an act of infringement by Mylan of one or more claims of the '771 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

187. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '771 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

188. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson Matthey.

189. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the '771 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

190. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

191. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '771 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

192. Upon information and belief, Defendants are aware of the existence of the '771 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '771 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

193. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

TWELFTH COUNT
(Infringement of the '466 Patent by Defendants)

194. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

195. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

196. Upon information and belief, Mylan included a paragraph IV certification to the '466 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '466 patent.

197. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

198. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

199. The inclusion of a paragraph IV certification to the '466 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '466 patent is an act of infringement by Mylan of one or more claims of the '466 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

200. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '466 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

201. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson Matthey.

202. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the '466 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

203. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

204. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '466 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

205. Upon information and belief, Defendants are aware of the existence of the '466 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '466 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

206. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

THIRTEENTH COUNT
(Infringement of the '467 Patent by Defendants)

207. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

208. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

209. Upon information and belief, Mylan included a paragraph IV certification to the '467 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '467 patent.

210. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

211. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

212. The inclusion of a paragraph IV certification to the '467 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '467 patent is an act of infringement by Mylan of one or more claims of the '467 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

213. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '467 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

214. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson Matthey.

215. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the '467 patent under 35 U.S.C. § 271(e)(2)(A)

indirectly in a cooperative venture, including by inducement and/or contributory infringement.

216. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

217. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '467 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

218. Upon information and belief, Defendants are aware of the existence of the '467 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '467 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

219. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

FOURTEENTH COUNT
(Infringement of the '619 Patent by Defendants)

220. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

221. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

222. Upon information and belief, Mylan included a paragraph IV certification to the '619 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '619

patent.

223. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

224. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

225. The inclusion of a paragraph IV certification to the '619 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '619 patent is an act of infringement by Mylan of one or more claims of the '619 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

226. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '619 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

227. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson Matthey.

228. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the '619 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

229. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

230. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '619 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

231. Upon information and belief, Defendants are aware of the existence of the '619 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '619 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

232. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

FIFTEENTH COUNT

(Infringement of the '305 Patent by Defendants)

233. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

234. Upon information and belief, Mylan seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Mylan Proposed Product.

235. Upon information and belief, Mylan included a paragraph IV certification to the '305 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '305 patent.

236. Upon information and belief, Mylan will commercially manufacture, sell, offer for sale, and/or import the Mylan Proposed Product upon, or in anticipation of, FDA approval.

237. Upon information and belief, as of the dates of the Mylan Notice Letters, Mylan was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

238. The inclusion of a paragraph IV certification to the '305 patent in ANDA No. 202835 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Proposed Product before the expiration of the '305 patent is an act of infringement by Mylan of one or more claims of the '305 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

239. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '305 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

240. Upon information and belief, as Johnson Matthey's DMF is the only DMF for lisdexamfetamine dimesylate identified on the FDA's website, the lisdexamfetamine dimesylate API in the Mylan Proposed Product is manufactured and supplied by Johnson

Matthey.

241. Upon information and belief, the inclusion of Johnson Matthey's written authorization in the Mylan ANDA for the purpose of supporting the Mylan ANDA is an act of infringement of one or more claims of the '305 patent under 35 U.S.C. § 271(e)(2)(A) indirectly in a cooperative venture, including by inducement and/or contributory infringement.

242. Upon information and belief, Johnson Matthey will commercially manufacture, sell, offer for sale, and/or import the lisdexamfetamine dimesylate API upon, or in anticipation of, FDA approval of the Mylan Proposed Product.

243. Upon information and belief, Johnson Matthey's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the lisdexamfetamine dimesylate API that will be used as the main component in the Mylan Proposed Product that is the subject of ANDA No. 202835 will infringe one or more claims of the '305 patent indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

244. Upon information and belief, Defendants are aware of the existence of the '305 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '305 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

245. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests the following relief:

i. A judgment declaring that the ’486 patent is valid and enforceable;

ii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the ’486 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

iii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the ’486 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

iv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the ’486 patent expires including any regulatory extensions;

v. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the

expiration of the ’486 patent including any regulatory extensions;

vi. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the ’486 patent;

vii. A judgment declaring that infringement of the ’486 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the ’486 patent;

viii. A judgment declaring that the ’735 patent is valid and enforceable;

ix. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the ’735 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

x. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the ’735 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xi. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the '735 patent expires including any regulatory extensions;

xii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the '735 patent including any regulatory extensions;

xiii. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '735 patent;

xiv. A judgment declaring that infringement of the '735 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '735 patent;

xv. A judgment declaring that the '630 patent is valid and enforceable;

xvi. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the '630 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xvii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the '630 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xviii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the '630 patent expires including any regulatory extensions;

xix. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the '630 patent including any regulatory extensions;

xx. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '630 patent;

xxi. A judgment declaring that infringement of the '630 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '630 patent;

xxii. A judgment declaring that the '253 patent is valid and enforceable;

xxiii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the '253 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xxiv. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the '253 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xxv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the '253 patent expires including any regulatory extensions;

xxvi. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the '253 patent including any regulatory extensions;

xxvii. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '253 patent;

xxviii. A judgment declaring that infringement of the '253 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '253 patent;

xxix. A judgment declaring that the '254 patent is valid and enforceable;

xxx. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the '254 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xxxi. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the '254 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xxxii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the '254 patent expires including any regulatory extensions;

xxxiii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the '254 patent including any regulatory extensions;

xxxiv. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '254 patent;

xxxv. A judgment declaring that infringement of the '254 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '254 patent;

xxxvi. A judgment declaring that the '787 patent is valid and enforceable;

xxxvii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the '787 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xxxviii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the '787 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xxxix. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the '787 patent expires including any regulatory extensions;

xl. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the '787 patent including any regulatory extensions;

xli. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '787 patent;

xlii. A judgment declaring that infringement of the '787 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '787 patent;

xliii. A judgment declaring that the '030 patent is valid and enforceable;

xliv. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the '030 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xlv. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the '030 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xlvi. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the '030 patent expires including any regulatory extensions;

xlvii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the '030 patent including any regulatory extensions;

xlviii. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '030 patent;

xlix. A judgment declaring that infringement of the '030 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '030 patent;

l. A judgment declaring that the '031 patent is valid and enforceable;

li. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the '031 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the '031 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

liii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the '031 patent expires including any regulatory extensions;

liv. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the '031 patent including any regulatory extensions;

lv. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '031 patent;

lvi. A judgment declaring that infringement of the '031 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '031 patent;

lvii. A judgment declaring that the '774 patent is valid and enforceable;

lviii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the '774 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lix. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the ’774 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lx. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the ’774 patent expires including any regulatory extensions;

lxi. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the ’774 patent including any regulatory extensions;

lxii. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the ’774 patent;

lxiii. A judgment declaring that infringement of the ’774 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the ’774 patent;

lxiv. A judgment declaring that the ’770 patent is valid and enforceable;

lxv. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the '770 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxvi. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the '770 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxvii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the '770 patent expires including any regulatory extensions;

lxviii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the '770 patent including any regulatory extensions;

lxix. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '770 patent;

lxx. A judgment declaring that infringement of the '770 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '770 patent;

lxxi. A judgment declaring that the '771 patent is valid and enforceable;

lxxii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the '771 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxxiii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the '771 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxxiv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the '771 patent expires including any regulatory extensions;

lxxv. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the '771 patent including any regulatory extensions;

lxxvi. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '771 patent;

lxxvii. A judgment declaring that infringement of the '771 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '771 patent;

lxxviii. A judgment declaring that the '466 patent is valid and enforceable;

lxxix. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the '466 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxxx. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the '466 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxxxi. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the '466 patent expires including any regulatory extensions;

lxxxii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the '466 patent including any regulatory extensions;

lxxxiii. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '466 patent;

lxxxiv. A judgment declaring that infringement of the '466 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '466 patent;

lxxxv. A judgment declaring that the '467 patent is valid and enforceable;

lxxxvi. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the '467 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxxxvii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the '467 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxxxviii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the '467 patent expires including any regulatory extensions;

lxxxix. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the '467 patent including any regulatory extensions;

xc. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the ’467 patent;

xci. A judgment declaring that infringement of the ’467 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the ’467 patent;

xcii. A judgment declaring that the ’619 patent is valid and enforceable;

xciii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the ’619 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xciv. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the ’619 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xcv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the ’619 patent expires including any regulatory extensions;

xcvi. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the '619 patent including any regulatory extensions;

xcvii. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '619 patent;

xcviii. A judgment declaring that infringement of the '619 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the '619 patent;

xcix. A judgment declaring that the '305 patent is valid and enforceable;

c. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202835 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 was an act of infringement of the '305 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

ci. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 prior to the expiration of the ’305 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

cii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202835 shall be no earlier than the date on which the ’305 patent expires including any regulatory extensions;

ciii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202835 and/or DMF No. 22442 until the expiration of the ’305 patent including any regulatory extensions;

civ. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the ’305 patent;

cv. A judgment declaring that infringement of the ’305 patent is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 202835 and/or DMF No. 22442 that infringes the ’305 patent;

cvi. A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Shire its attorneys' fees and costs;

cvii. Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

s/ Michael R. Griffinger

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